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Principal Investigator

29 September, 1997

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## 5. Introduction

### A. Background:

Urodynamics, a term coined over thirty years ago, encompasses investigations used for assessing lower urinary tract function. However, the tests are generally performed under non-physiological circumstances in anxiety provoking clinical settings where information is usually available from only one filling and voiding cycle. Although artificial filling cystometry (CMG) has long been the standard method of investigating lower urinary tract function, several factors limit the reliability of the data, to include: non-physiological rates of bladder filling, short duration of the test, urethral catheterization, and the degree of immobility imposed by the urodynamic apparatus.

There have been many attempts to overcome the limitations of conventional cystometry by developing more physiological methods of urodynamic testing. These have included telemetry, using standard urethral catheterization (1) or intravesical radio transducers to overcome urethral irritation (2). Recent technological advances in micro-transducers and portable data storage devices have led to wider usage of ambulatory urodynamic monitoring.

It has become apparent that differences exist between values obtained from stationary urodynamic studies with artificial filling and natural filling ambulatory urodynamic systems. Robertsen (3) reported significantly higher detrusor pressure rises during filling with conventional cystometry than on natural bladder filling with ambulatory monitoring.

Several authors have reported an increase in detrusor activity recorded on ambulatory monitoring as compared to conventional cystometry (4 - 6) in both symptomatic and asymptomatic patients. There is debate as to whether this increased activity is an artifact produced by factors to include catheter irritation, or if it truly represents detrusor instability. It is also possible that phasic detrusor activity, especially during intense ambulation, is a physiologic finding.

Several authors including Robertsen (3) have reported lower voided volumes on ambulatory monitoring compared with conventional cystometry. Residual volumes are also reported as lower on ambulatory monitoring than conventional cystometry. Robertsen suggested that this may relate to the desensitization of the detrusor during the rapid filling of the conventional cystometry, and that the upright posture of the ambulant subject may increase the desire to micturate as well as the efficiency of the detrusor contraction.

The voiding pressures have been widely reported as significantly greater on ambulatory monitoring than on conventional cystometry (3, 4). Van Waalwijk (4) concluded that this increased activity was not artifactual, based on subjective assessment of the discomfort by the catheters to the volunteers during ambulatory testing.

Turner -Warwick (5) estimated that over 10% of adults never completely develop an adult pattern of voiding, and maintain detrusor instability at a level that is either asymptomatic or

is not troublesome enough to seek help.

Van Waalwijk (4) and Heslington (6) both compared the incidence of detrusor instability between asymptomatic female volunteers recorded on conventional and ambulatory cystometry. Using the International Continence Society Committee on Standardization of Terminology's definition of unstable detrusor as "one that is shown objectively to contract, spontaneously or on provocation during the filling phase while the patient is attempting to inhibit micturition," both authors found that 18% of asymptomatic female volunteers exhibited unstable detrusor contractions of amplitudes from 3-13cm water on conventional cystometry. On ambulatory monitoring 69% and 68% of the volunteers respectively showed detrusor instability of a similar magnitude.

The definition of unstable detrusor makes no reference to the amplitude or the frequency of contractions, although an amplitude of 15cm water or greater, is commonly taken to be indicative of detrusor instability by clinicians. When Heslington (6) compared detrusor contractions of 15cm water or greater, the percentage of asymptomatic female volunteers who demonstrated these on conventional cystometry was actually 9% and ambulatory monitoring was 41%.

The consistency with which there is increased detrusor activity on ambulatory monitoring in asymptomatic groups makes interpretation of the activity in symptomatic patients difficult. However, several investigators (7, 8) have found ambulatory monitoring in symptomatic patients useful. In these studies, patients with suspected, but unproven detrusor instability on conventional testing were found to have demonstrable detrusor instability in 40 - 84% of the time. But since these rates are similar to those found in asymptomatic volunteers, can we regard the activity as significant, and more practically, should we base treatment decisions on their results?

Recent investigators have attempted to find ways to interpret this data in a manner yielding more clinical significance. Van Waalwijk and Van Dooren (9) quantified detrusor over-activity by a detrusor activity index, incorporating the frequency and amplitude of contractions. They found that patients with mixed incontinence had a higher index than those with stress incontinence, or asymptomatic subjects. In spite of these limitations ambulatory urodynamics remain the most reliable system for evaluating bladder function during physical activity (10).

In a previous study, we had identified a number of female soldiers who complained of severe urinary incontinence during physical training or field duty, but appeared urodynamically normal on conventional cystometry. These soldiers generally complained only of exercise induced urinary incontinence, and had few complaints of incontinence during their regular duties or daily lives.

Many studies have shown pelvic muscle exercises in combination with vaginal electromyographic (EMG) biofeedback to be an effective way to treat urinary incontinence in the elderly (11-13). We (14) showed this treatment to be effective for treating female soldiers reporting exercise induced urinary incontinence.

### **B. Purpose:**

To evaluate female soldiers who complained primarily of exercise induced urinary incontinence and compare urodynamic findings from conventional urodynamic studies, and ambulatory studies obtained during the activity which actually precipitated the incontinence. We also wished to determine if information obtained from these tests, either separately or in conjunction with each other, would enable us to achieve improvement of the soldiers' urinary incontinence during physical activity.

No studies have been done to objectively evaluate the urodynamic characteristics of exercise induced urinary incontinence during the actual activity which produces the incontinence. All previous studies have been based on the attempted reproduction of the event which produced the incontinence in hospital based laboratory conditions.

This team has previously studied the effectiveness of behavioral interventions for treatment of stress urinary incontinence among female soldiers (14) and found that the group is highly responsive and the treatments to be very effective.

### **C. Hypotheses:**

1. That ambulatory urodynamic testing is more sensitive than conventional, in-clinic urodynamic testing for detection of exercise induced urinary incontinence among female soldiers.
2. That behavioral intervention (Kegal exercises in combination with vaginal EMG biofeedback) is effective treatments for this population and will result in normalization of the urodynamic recordings.

## **6. Body**

### **A. Methods**

Fifty active duty female volunteers with exercise induced urinary incontinence, and ten asymptomatic controls were recruited by means of a poster from the female soldiers at Ft. Lewis, Washington, from June 1996 through June 1997.

Each subject initially underwent a standard evaluation of the lower urinary tract to include a detailed genitourinary history, physical, and neurologic examinations. The urodynamic evaluation included uroflometry, with post-void residual urine volume measurement, retrograde provocative water cystometry, resting and stressed urethral axis determination, and direct visualization testing of fluid loss with stress. Urethral pressure profilometry with urethral closure pressures were also performed. Urodynamic evaluations (UCMG's) were performed using the Life-Tech 1711 UROFLOW urodynamic system (P.O. Box 36221, Houston, TX, 77236) which has the capability to record abdominal, vesical, urethral, and detrusor pressures. The system is additionally able to perform uroflometry with post void residual urine volume measurement,

retrograde provocative water cystometry, resting and stressed urethral axis determination and direct visualization testing for fluid loss with stress.

The subjects were then evaluated one week later with ambulatory cystometric recordings. They were fitted with the UPS 2020 ambulatory measurement system (Medical Measurement Systems, B.V. Holland, Boston). The intravesical and intravaginal pressures were recorded with flexible 3mm microtip transducers (Millar, Houston, Texas) inserted 6cm from the urethral meatus and above the levator plate vaginally. The subjects were given instructions to record events on the keyboard of the UPS 2020 system as they occurred, and to proceed with the work or exercise which commonly produced their urinary incontinence. The asymptomatic subjects were instructed to wear the device during their normal workday. The subjects were asked to record for six continuous hours. All subjects were instructed to eat and drink as they usually did and neither force nor restrict fluids. All subjects were given one dose of a prophylactic antibiotic when the catheters were removed (Macrochantin, 100mg. P.O.).

The ambulatory recordings were reviewed by staff gynecologists at Madigan Army Medical Center, Ft. Lewis, Washington, and those with uninhibited detrusor contractions recording >1 5cm water were referred for biofeedback.

All subjects were given standard instructions for performing Kegel exercises with the assistance of the I-410 J&J Biofeedback system (22797 Holgar Ct. N.E., Poulsbo, WA 98370) which was connected to a 486 IBM compatible computer containing the software designed for this system. Perry-vaginal sensors (MODEL #SRS-4509, 14770 N.E. 95th St. Redmond, WA 98052) picked up EMG (electromyographic) activity from the pelvic floor muscles while additional adhesive sensors were attached to the abdomen to measure abdominal EMG. The in laboratory training protocol consisted of a 10 second contraction/10 second relaxation repeated 5 times within each trial, with a 30 second break between each of the 5 trials. Patients were told to contract the pelvic floor muscles while trying to keep the abdominal, gluteal, and thigh muscles relaxed. The EMG signals of both their pelvic floor muscles (in blue) and their abdominal muscles (in red) were displayed on the computer screen. Subjects were instructed to keep the red line at baseline by relaxing the abdominal muscles while raising the blue line by contracting the pelvic floor muscles. They were asked to maintain the contraction for the entire ten seconds and then to relax all muscles so that both lines returned to baseline. During at least one of the sessions, the therapist would leave the room so the patient could practice the Kegels without performance anxiety. The patients were also asked to practice the Kegels while looking away from the computer screen to assure that they were practicing the exercises correctly at home.

For home practice, all patients were instructed to practice the Kegel exercises (10 second contraction/10 second relaxation) for twenty minutes two times a day. They were given a MyoTrac2 (Thought Technology, Inc.; 22797 Holgar Ct. N.E., Poulsbo, WA 98370) biofeedback home training device to take with them for the first week and use in conjunction with their home exercises.

At the end of a two month interval all subjects were re-evaluated by standard cystometry and ambulatory cystometry as before, and the results compared. All subjects were asked to complete a questionnaire upon entering and on completion of the study. The questionnaire



addressed basic demographics including age, parity, height, weight, and race. In addition, subjects were asked to rate their urinary loss as (a) minimal or no incontinence, (b) mild incontinence, or (c) severe incontinence.

## **B. Results:**

Sixty-two female soldiers with exercise induced urinary incontinence started participation but twelve dropped out due to transfers and other reasons. Thus, fifty soldiers with incontinence problems and ten asymptomatic controls completed the project.

The mean age of the fifty incontinent subjects was 31.9 (SD= 6.21) years while that of the controls was 36.4 (SD= 4.58) years. The mean weight of the incontinent subjects was 140.1 (SD= 22.92) relative to 143.0 (SD = 37.02) for the controls. The mean height of the incontinent subjects was 64.6 inches (SD= 3.18) relative to 63.4 (SD = 2.14) for the controls. The mean number of vaginal deliveries for the incontinent subjects was 1.4 (SD= 1.18) relative to 1.5 (SD = 0.50) for the controls. There were no significant differences in height, weight, age, or parity between the two groups.

The data were analyzed for significance by independent samples "T" tests. Of the 50 subjects who complained of exercise induced urinary incontinence, 41 (82%) demonstrated no abnormalities on conventional cystometry. Nine demonstrated evidence of uninhibited detrusor contractions of an amplitude of 15cm water or greater. Thirty-eight (92%) of the 41 subjects with no demonstrable detrusor contractions during conventional cystometry demonstrated them during ambulatory cystometry with a mean rate of 0.92 uninhibited detrusor contractions per hour. Seven (78%) of those nine subjects who did demonstrate detrusor dysfunction at conventional cystometry also demonstrated them during ambulatory cystometry with a mean rate of 0.51 contractions per hour. Conventional urodynamic cystometry showed a sensitivity of only 18% but a specificity of 100% in detecting exercise induced urinary incontinence. Ambulatory urodynamic cystometry showed a sensitivity of 96% and a specificity of 80%. Thus, ambulatory recordings are better at detecting the problem but not quite as accurate in differentiating normal controls from those with the problem.

Overall, only 18% of those subjects who complained of exercise induced urinary incontinence demonstrated any cystometric abnormalities on conventional (in-clinic) testing, but 96% demonstrated abnormal detrusor contractions during ambulatory studies. None of the ten asymptomatic controls showed any detrusor dysfunction on conventional urodynamic evaluation and two (20%) demonstrated rare detrusor dysfunction on ambulatory monitoring, with a rate of 0.2 per hour (These data are detailed in Table I).

All 41 subjects who initially tested as normal on conventional cystometry still appeared normal upon repeat conventional cystometry after biofeedback therapy. However, 18 (44%) of these 41 demonstrated complete elimination of detrusor dysfunction during ambulatory recordings after biofeedback therapy. The frequency of uninhibited detrusor contractions on ambulatory monitoring was reduced with biofeedback from 0.92 per hour to 0.35 per hour in this group.

Of the nine subjects with demonstrable detrusor contractions on initial conventional

cystometry, seven (77%) showed no evidence of detrusor disfunction when the study was repeated after biofeedback intervention. Three of the nine (33%) showed no evidence of detrusor disfunction during ambulatory recordings after biofeedback. The frequency of uninhibited detrusor contractions on ambulatory monitoring was reduced with biofeedback from 0.51 per hour to 0.22 per hour in this group.

The subjective ratings of urinary incontinence by both groups were compared before and after treatment. Of those 41 subjects with no demonstrable abnormalities on conventional cystometry, 33 subjects or 81% rated their urine loss as severe. After biofeedback 5 subjects or 12 % still rated their urine loss as severe. Of those nine subjects with demonstrable detrusor contractions on cystometry eight or 89% initially rated their urine loss as severe and after biofeedback no subject in this group still rated their urine loss as severe. The improvement of subjective ratings of urinary incontinence was significant in both groups ( $P < 0.05$ ).

Both groups who complained of exercise induced urinary incontinence (those with normal and abnormal conventional cystometry) initially demonstrated significantly more uninhibited detrusor contractions on ambulatory cystometry than controls, 0.92 per hour, 0.51 per hour, and 0.2 per hour respectively ( $P < 0.05$ ).

Subjects who complained of urinary incontinence were more likely to demonstrate detrusor dysfunction on conventional cystometry than controls (18% vs. 0%). All subjects who complained of exercise induced incontinence showed a significant decrease in number of leaks per day after biofeedback with a change from 3.83 leaks per day to 1.83 ( $p < 0.05$ ). Initially, all of the subjects complained of urinary incontinence during physical training. After biofeedback 75 percent still reported leakage but subjectively reported less leakage when it occurred. Initially, 85 percent of the subjects experienced an urge to void during exercise. After biofeedback 70 percent still reported this urge. Paired t-tests also showed that the frequency of urination decreased significantly ( $p = .01$ ) for the 41 subjects who were normal on stationary cystometrograms but not for the nine subjects who demonstrated detrusor disfunction on stationary cystometrograms. The maximum voluntary contraction of pelvic floor muscles (as reflected by vaginal surface EMG) changed from a mean of 18.7 microvolts ( $SD = 10.62$ ) to a mean of 26.25 ( $SD = 12.16$ ) microvolts ( $p = 0.03$ ). The ability to sustain a maximal contraction did not increase with treatment.

Table one summarizes the comparison of conventional vs. ambulatory cystometry in the detection of detrusor activity.

**C. Portion of the study at Ft. Benning:** This portion of the study was not performed as it was not approved by Fort Benning's IRB due to safety concerns about soldiers jumping while wearing the device. The study was over by the time we were able to provide the required safety documentation.

**Table I**

comparison of conventional vs. ambulatory cystometry  
in the detection of detrusor activity

Incontinent		Asymptomatic	
Conventional Cystometry	Ambulatory Cystometry	Conventional Cystometry	Ambulatory Cystometry
18%	96%	0%	20%

### C. Discussion

Exercise induced urinary incontinence is a pervasive problem among the female soldier. Over 30% of female soldiers report that they commonly experience urinary incontinence during field duty or physical training which is of enough significance to be a hygienic or social problem. Urinary incontinence poses challenges to the female soldier which are unparalleled in her civilian counterpart. These soldiers have limited options when duty or physical training subjects them to conditions which predispose them to incontinence. In addition, field conditions often provide limited access to hygienic measures commonly utilized by the incontinent patient. In cold weather field conditions, urinary incontinence can pose severe hazards and at least impact the soldiers' quality of life, and her ability to effectively accomplish her duties.

Considering the importance of early detection and treatment, we were concerned that a significant number of female soldiers complained of urinary incontinence during physical exertion, and yet appeared urodynamically normal upon conventional laboratory testing. These soldiers had traditionally been offered little further therapy for their incontinence. This study showed that conventional urodynamic studies, performed in a laboratory setting, do not duplicate the conditions which lead to exercise induced urinary incontinence, and only detected urodynamic abnormalities in 18% of those symptomatic subjects tested. Ambulatory monitoring demonstrated significant abnormalities in 96% of these soldiers.

The patient's history of urinary incontinence has traditionally proven inaccurate in determining the type of incontinence from which she suffers, i.e., genuine stress incontinence, urge incontinence, or mixed incontinence (15). Many authorities have insisted that objective data obtained from conventional urodynamic studies be obtained before definitive therapy, whether surgical, behavioral, or pharmacological, is instituted.

Wahl (16) however, suggested that the institution of behavioral therapy for urinary incontinence before sophisticated (multichannel) urodynamic testing was cost-effective. Karram, (17) in a similar study of non-surgical therapy for urinary incontinence concluded that "although we think that an objective assessment of incontinence is necessary prior to surgical correction, the study showed, in a retrospective fashion, that it is not efficacious nor cost-effective for a woman to undergo electronic urodynamic testing prior to initiating non-surgical therapy. Benefits of conservative therapy were noted in patients with stress incontinence, mixed incontinence, and detrusor instability."

The results of this study support those findings. If therapy had been instituted only on those subjects who showed abnormalities on conventional urodynamic testing, 41 out of the 50 subjects who complained of exercise-induced urinary incontinence would have received no further treatment. Further confirmation of the effectiveness of behavioral interventions with this group is provided by the success of our initial use of this intervention with female soldiers (11).

Ironically, the subjects with exercise induced incontinence and normal conventional cystometry demonstrated significantly greater numbers of uninhibited bladder contractions on ambulatory cystometry than those who actually had demonstrable detrusor dysfunction on

conventional cystometry (0.92 per hour vs. 0.51 per hour) but the number of subjects is small ( $P < 0.05$ ). Both groups showed marked improvement in both subjective and objective measures of continence after biofeedback.

We conclude, as did Karram (17), that it is not efficacious or cost-effective for a female soldier to undergo conventional electronic urodynamic testing prior to the initiation of nonsurgical therapy for urinary incontinence. This study supports the same conclusion with regard to ambulatory urodynamic testing.

The majority of patients who complain of exercise induced urinary incontinence can be effectively managed by conservative therapy. If conservative therapy proves unsatisfactory, then conventional urodynamic testing and possibly ambulatory urodynamic testing appear indicated.

## **7. Conclusions**

Exercise induced urinary incontinence is a pervasive problem among female soldiers, and poses challenges which are unparalleled among their civilian counterparts. We have shown that conventional, stationary (in-clinic) urodynamic testing, although considered to be the gold standard, is not a sensitive test for the detection of exercise induced urinary incontinence. Ambulatory testing is a very sensitive test for this problem, and can lead to earlier detection and institution of appropriate treatment.

Behavioral interventions consisting of Kegal exercises combined with vaginal EMG biofeedback were highly successful in eliminating detrusor dysfunction and treating the disorder.

It is neither cost effective nor efficacious to require sophisticated urodynamic testing before instituting behavioral interventions.

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